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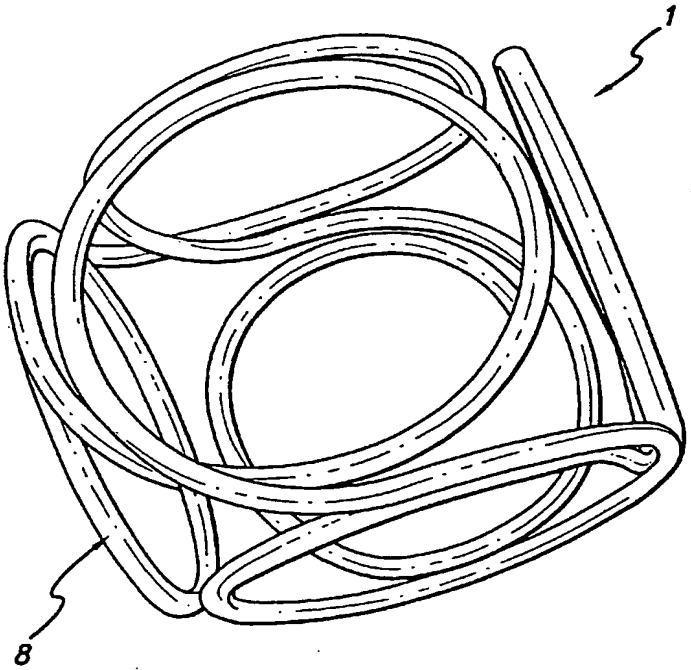

(57) Abstract: The three dimensional, low friction vasoocclusive coil has a portion that is three dimensionally box or cubed shaped. The three dimensional box or cubed shaped portion will form a basket for filling the anatomical cavity at the site in the vasculature to be treated. The vasooclusive device is formed from at least one strand of a flexible material formed to have a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated. The vasoocclusive coil may optionally include a portion that is substantially J-shaped or helically shaped, for filling and reinforcing the three dimensional portion.

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THREE DIMENSIONAL, LOW FRICTION COIL, AND METHOD OF MANUFACTURE

BACKGROUND OF THE INVENTION

Field of the Invention:

This invention relates generally to vasoocclusive devices, and more particularly concerns a vasoocclusive device that has a first elongated, reduced friction configuration in which the vasoocclusive device may be deployed through a catheter or cannula to an anatomical cavity at a site in the vasculature to be treated, and that has a three dimensional second configuration assumed by the vasoocclusive device at the site to be treated for filling the anatomical cavity.

Description of Related Art:

The art and science of interventional therapy and surgery has continually progressed towards treatment of internal defects and diseases by use of ever smaller incisions or access through the vasculature or body openings in order to reduce the trauma to tissue surrounding the treatment site. One important aspect of such treatments involves the use of catheters to place therapeutic devices at a treatment site by access through the vasculature. Examples of such procedures include transluminal angioplasty, placement of stents to reinforce the walls of a blood vessel or the like and the use of vasoocclusion devices to treat defects in the vasculature. There is a constant drive by those practicing in the art to develop new and more capable systems for such applications. When coupled with developments in biological treatment capabilities, there is an expanding need for technologies that enhance the performance of interventional therapeutic devices and systems.

One specific field of interventional therapy that has been able to advantageously use recent developments in technology is the treatment of neurovascular defects. More specifically, as smaller and more capable structures and materials have been developed, treatment of vascular defects in the human brain which were previously untreatable or represented unacceptable risks via conventional surgery have become amenable to treatment. One type of non-surgical therapy that has become advantageous for the treatment of defects in the neurovasculature has been the placement by way of a catheter of vasoocclusive devices in a damaged portion of a vein or artery.

Vasoocclusion devices are therapeutic devices that are placed within the vasculature of the human body, typically via a catheter, either to block the flow of blood through a vessel making up that portion of the vasculature through the formation of an embolus or to form such an embolus within an aneurysm stemming from the vessel. The vasoocclusive devices can take a variety of configurations, and are generally formed of one or more elements that are larger in the deployed configuration than when they are within the delivery catheter prior to placement. One widely used vasoocclusive device is a helical wire coil having a deployed configuration which may be dimensioned to engage the walls of the vessels.

The delivery of such vasoocclusive devices can be accomplished by a variety of means, including via a catheter in which the device is pushed through the catheter by a pusher to deploy the device. The vasoocclusive devices, which can have a primary shape of a coil of wire that is then formed into a more complex secondary shape, can be produced in such a way that they will pass through the lumen of a catheter in a linear shape and take on a complex shape as originally formed after being deployed into the area of interest, such as an aneurysm. A variety of detachment mechanisms to release the device from a pusher have been developed and are known in the art.

For treatment of areas of the small diameter vasculature such as a small

artery or vein in the brain, for example, and for treatment of aneurysms and the like, micro-coils formed of very small diameter wire are used in order to restrict, reinforce, or to occlude such small diameter areas of the vasculature. A variety of materials have been suggested for use in such micro-coils, including nickel-titanium alloys, copper, stainless steel, platinum, tungsten, various plastics or the like, each of which offers certain benefits in various applications. Nickel-titanium alloys are particularly advantageous for the fabrication of such micro coils, in that they can have super-elastic or shape memory properties, and thus can be manufactured to easily fit into a linear portion of a catheter, but attain their originally formed, more complex shape when deployed.

One conventional vasoocclusive coil is known, for example, that has a three dimensional in-filling coil configuration, formed by winding a wire into a helix, and then winding the helix into a secondary form which forms a generally spherical shape, by winding the primary coil about poles placed on winding mandrel. The secondary wound coil is then annealed on the winding mandrel, and the coil is then removed from the winding mandrel and loaded into a carrier for introduction into a delivery catheter. Another similar type of vasoocclusive device is known that can be formed from one or more strands, and can be wound to form a generally spherical or ovoid shape when released and relaxed at the site to be treated. Another implantable vasoocclusive device having multiple secondary layers of primary windings has a final shape that is a generally spherical coil formed of linear or helical primary coils that are wound into a secondary form having three layers. The inner winding is wound and then the second layer formed by winding in the opposite direction of the first layer. The final configuration is a chunky or stepped shape approximately a sphere, ovoid, or egg. Yet another conventional implant for vessel occlusion is made from helical elements of metal or synthetic material by twisting or coiling the elements and forming them into a secondary shape such as a rosette or double rosette for implantation using a catheter, and another vasoocclusive device is known that has a final conical shape.

However, due to the tendency of such three dimensional shaped coils to transform into their expanded, final forms when introduced into a catheter in the body, they are inherently more difficult than a helical coil or a straight wire or micro-cable to push through such a catheter for delivery to a site in the vasculature to be treated, due to friction between the coil and the catheter through which it is delivered to the site to be treated, which can even result in misalignment of the coil within the catheter during delivery.

There thus remains a need for a vasoocclusive device that has a three dimensional final form that can be used to fill an anatomical cavity at a site in the vasculature to be treated, reduces friction between the coil and the catheter through which it is delivered to the site to be treated, and ultimately helps to prevent coil misalignment. The present invention meets these and other needs.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention provides for an improved vasoocclusive coil, that has a three dimensional box or cube-shaped portion, and a method of making the coil. The three dimensional portion will form a basket for filling the anatomical cavity at the site in the vasculature to be treated. The three dimensional portion of the vasoocclusive coil comprises at least one strand of a flexible material formed to have an a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional box or cube-shaped configuration for occluding the desired portion of the vasculature to be treated. This substantially linear configuration allows for reduction of friction of the coil within a catheter or cannula being used to deliver the vasoocclusive coil to the site in the vasculature to be treated, and ultimately helps prevent coil realignment or misalignment. The ultimate coil volume that otherwise might be limited due to

frictional constraints of three dimensional coils will not be compromised with the device of the present invention. The vasoocclusive coil may optionally also include a portion having a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable configuration that is substantially J-shaped or helically shaped, for filling and reinforcing the three dimensional box or cube-shaped basket portion, for occluding the desired portion of the vasculature to be treated, in order to combine the best qualities of a three dimensional coil and a J-shaped or helical coil.

The present invention accordingly provides for a vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery. The vasoocclusive device comprises at least one strand of a flexible material formed to have a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated. The vasoocclusive device advantageously has a portion having a second operable, three dimensional box or cube shape for filling the anatomical cavity at the site in the vasculature to be treated, and may optionally include a portion having a second operable, substantially J-shape or helical shape for filling and reinforcing the distal, three dimensional box or cube shaped portion when it is implanted at the site in the vasculature to be treated.

The present invention also provides for a method of making the vasoocclusive device. The method generally comprises the steps of winding at least one strand of a flexible shape memory material about a mandrel formed of a refractory material in a three dimensional configuration of the vasoocclusive coil to form a distal portion of the vasoocclusive coil; heating the at least one strand of a flexible shape memory material wound about the mandrel for a sufficient period of time to impart the form to the shape memory material included in the device to form an operable, three

dimensional configuration of the vasoocclusive coil; removing the vasoocclusive coil from the mandrel; and cold working the vasoocclusive coil into a desired elongated configuration for placement into a catheter or cannula for use. In one presently preferred embodiment, the mandrel about which the at least one flexible strand forming the vasoocclusive coil is wound has a substantially orthogonal or cubical body with a plurality of posts disposed on the body. In a preferred aspect, six posts are disposed on the body aligned with the three orthogonal x, y and z axes through the body of the mandrel, for aligning and shaping the box or cube shaped portion of the vasoocclusive device as it is wound on the mandrel. In one presently preferred embodiment, one of the posts is provided with a handle that can optionally also be used as a mandrel for winding a portion of the vasoocclusive coil with a helical shape. In another preferred aspect of the method, the step of heating comprises heating the at least one strand of a flexible shape memory material wound about the mandrel at a temperature of about 1100° F for at least about 4 hours to impart the form to the shape memory material included in the device to form an operable, three dimensional configuration of the distal portion of the vasoocclusive coil.

These and other aspects and advantages of the invention will become apparent from the following detailed description and the accompanying drawings, which illustrate by way of example the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a cross section of a vascular member with an aneurysm illustrating the approach of a vasoocclusive coil towards the aneurysm.

Figure 2 is a side elevational view showing a first embodiment of a second operable, three dimensional configuration of the vasoocclusive coil of the invention.

Figure 3A is a side elevational view showing a first option of the first

embodiment of Figure 2, including a two-dimensional substantially J-shaped portion.

Figure 3B is a side elevational view showing a second option of the first embodiment of Figure 2, including a helically shaped portion.

Figure 4 is a perspective view of a radiopaque microstrand cable used in forming the vasoocclusive coil according to the invention.

Figure 5 is a cross-section at 5-5 of Figure 4.

Figure 6 is an alternate preferred embodiment of the invention including a plurality of radiopaque strands within the cable.

Figure 7 is an alternate preferred embodiment of the present invention wherein strands of the cable are arranged within an exterior binding consisting of multiple straps about the cable.

Figure 8 is a perspective view of the embodiment of Figure 7.

Figure 9 is an alternative embodiment to the embodiment of Figure 8 wherein the external binding of the cable represents a sheath wound about the cable.

Figures 10a and 10b are perspectives of alternative embodiments of the embodiment of Figure 9.

Figure 11 is a cross-section of an alternative embodiment in which a plurality of multi-strand cables are included within an external sheath surrounding the cable.

Figure 12 is a perspective view of the embodiment of Figure 11.

Figure 13 is a perspective view of a first embodiment of a mandrel used for making the vasoocclusive coil according to the method of the invention.

Figure 14 is a plan view of the mandrel of Figure 13.

Figure 15 is a sectional view of the mandrel of Figure 13 taken along line 15-15 of Figure 14.

Figure 16 is a perspective view of a second embodiment of a mandrel used for making the vasoocclusive coil according to the method of the invention.

Figure 17 is a plan view of the mandrel of Figure 16.

Figure 18 is a sectional view of the mandrel of Figure 16 taken along line 18-18 of Figure 17.

Figure 19 is a perspective view of a third embodiment of a mandrel used for making the vasoocclusive coil according to the method of the invention.

Figure 20 is a perspective view of a second operable, three dimensional configuration of the vasoocclusive coil of the invention formed over the mandrel of Figure 19 according to the method of the invention.

Figure 21 is a perspective view showing a second operable, three dimensional configuration of the vasoocclusive coil formed over the mandrel of Figure 19 according to the method of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

While conventional three dimensional and spherical vasoocclusive coils have been developed, such three dimensional shaped coils tend to transform into their expanded, final forms when introduced into a catheter in the body, making them inherently more difficult than a simple helical coil or straight wire to push through a catheter or cannula for delivery to a site in the vasculature to be treated, due to friction between the coil and the catheter through which it is delivered to the site to be treated, and that can even result in misalignment of the coil within the catheter during delivery.

As is illustrated in the drawings, the invention is accordingly embodied in a vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery. The vasoocclusive coil 1 is formed from at least one strand of a flexible material formed to have a first inoperable, substantially linear configuration, as illustrated in Figure 1, for insertion through a micro-catheter 2 into a desired portion of the vasculature to be treated, such as an aneurysm, or other anatomical malformation of the vasculature to be treated, and a second operable, three dimensional configuration

illustrated in Figures 2, 3A and 3B, for occluding the desired portion of the vasculature to be treated.

Figure 1 illustrates a helically wound vasoocclusive coil 1 which is formed to fit within the micro-catheter for insertion into an area upon which a therapeutic procedure is to be performed. Figure 1 further shows a catheter pusher member 3 for delivering a vasoocclusive coil 1 for insertion into an aneurysm 4 projecting laterally from a blood vessel 5. The end of the micro-catheter 2 is typically introduced into the opening of the aneurism by use of a guide wire (note shown), and the coil and pusher member are introduced into the micro-catheter to insert the vasoocclusive coil into the aneurysm. In a presently preferred embodiment, catheter pusher member to which the vasoocclusive coil is mounted is an optical fiber pusher which is attached to the coil by a collar 6 of shape memory material such as a nickel titanium super-elastic alloy, or a shape memory polymer, for example. The vasoocclusive coil is typically introduced into the aneurysm and is then pushed from the micro-catheter until the vasoocclusive coil fills the cavity.

In one presently preferred embodiment, the shape memory collar 6 is heated to a temperature which allows it to be shrunk onto the vasoocclusive coil. The collar can be attached to optical fiber pusher by an adhesive which retains high strength at temperatures beyond the shape memory material transition point. After insertion, and when an operator is satisfied that the device is properly deployed, light energy from a source of coherent light is introduced into the proximal end of the optical fiber (not shown) and propagated in the distal end 7 of the fiber to cause the shape memory material collar to return to its previous shape and release the vasoocclusive coil. Those skilled in the art will recognize that the invention can also be used with a variety of other placement catheter systems, and it is not intended that the invention be limited to the placement concepts illustrated by way of example.

Referring to Figures 2, 3A and 3B, the vasoocclusive device preferably has a portion 8 having a second operable, three dimensional shape for filling the

anatomical cavity at the site in the vasculature to be treated. As is illustrated in Figure 2, in a presently preferred embodiment, the three dimensional portion of the vasoocclusive device is orthogonal, having a box or cube shape for filling the anatomical cavity at the site in the vasculature to be treated.

As is illustrated in Figure 3A, in one presently preferred option of the embodiment of Figure 2, the vasooclusive device may also include a portion 9 having a second operable, substantially J-shaped coil shape, for filling and reinforcing the distal, three dimensional shaped portion 8 when the vasoocclusive device is implanted at the site in the vasculature to be treated.

As is illustrated in Figure 3B, in one presently preferred option of the embodiment of Figure 2, the vasooclusive device may also include a portion 9' having a second operable, substantially helical coil shape, for filling and reinforcing the distal, three dimensional shaped portion 8 when the vasoocclusive device is implanted at the site in the vasculature to be treated.

In a presently preferred aspect of the invention, the vasoocclusive coils are formed from a single strand of flexible platinum wire, formed to have an a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated. The vasoocclusive coils may also be made from a multi-stranded micro-cable, formed to have an a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated. The multi-stranded micro-cable may be formed from a wide variety of materials, including stainless steels if some sacrifice of radiopacity may be tolerated. Very desirable materials of construction, from a mechanical point of view, are materials which maintain their shape despite being subjected to high stress. Certain "super-elastic alloys" include nickel/titanium alloys

(48-58 atomic % nickel, and optionally containing modest amounts of iron); copper/zinc alloys (38-42 weight % zinc); copper/zinc alloys containing 1 - 10 weight % of beryllium, silicon, tin, aluminum, or gallium; or nickel/aluminum alloys (36-38 atomic % aluminum). Particularly preferred are the alloys described in U.S. Patent Nos. 3,174,851; 3,351,463; and 3,753,700. Especially preferred is the titanium/nickel alloy known as nitinol. These are very sturdy alloys which will tolerate significant flexing without deformation even when used as a very small diameter wire. Additionally, the strand may be constructed of a polymer, such as polyvinyl alcohol foam, for example. The wire should be of sufficient diameter to provide a hoop strength to the resulting device sufficient to hold the device in place within the chosen body cavity without distending the wall of the cavity and without moving from the cavity as a result of the repetitive fluid pulsing found in the vascular system. Should a super-elastic alloy such as nitinol be used, the diameter of the coil wire can be significantly smaller than that used when the relatively ductile platinum or platinum/tungsten alloy is used as the material of construction.

As is illustrated in Figure 4, the vasoocclusive coils may be formed from a multi-stranded micro-cable 10 that is typically approximately from .0021 to .0045 inches in diameter, and comprises a plurality of flexible strands 12 of nickel-titanium alloy, with at least one centrally, axially disposed radiopaque wire 14 which is approximately from .0007 to .0015 inches in diameter. While the above stated diameters represent those presently known to be compatible with the invention, larger or smaller diameters may be useful for particular applications.

The central radiopaque wire 14 can be formed of platinum or gold, for example, other similar suitable radiopaque metals, or other suitable types of radiopaque materials, in order to provide a radiopaque marker of the deployed configuration of a device made of the cable during vascular surgery. The radiopaque material may be a metal or a polymer. Suitable metals and alloys for the wiring include platinum group metals, especially platinum rhodium, palladium, as well as tungsten, gold, silver,

tantalum, and alloys of these metals. Highly preferred is a platinum/tungsten alloy.

There are numerous benefits to the novel construction of the invention for use in interventional devices and the like. By using the stranded or micro-cable construction of the invention, a vasoocclusive device made from the micro-cable becomes virtually kink resistant compared to the single strand wires now commonly used in micro-coils. The multi-strand cable construction of the invention allows the micro-wires of the cable to slip across each other and reinforce each other rather than break or take a set. Also, by incorporating a stranded radiopaque material such as platinum, tungsten or gold into the cable construction, the device is radiopaque in sizes much smaller than with other constructions.

Figure 5 is a cross-section of the micro-cable of Figure 4 at 5-5 illustrating one presently preferred arrangement of the strands within the cable. In this embodiment, the exterior strands 12 are formed of a resilient material chosen to provide the characteristics desired for a specific application in interventional therapies. In a presently preferred embodiment, this material is a nickel titanium super-elastic alloy which is heat treated such that the alloy is highly flexible at a temperature appropriate for introduction into the body via a catheter or cannula. By choosing such a material for micro-coils and the like, the devices formed from the micro-cable can be relatively easily placed into the appropriate body cavity and after placement, the device will take on a shape designed to optimize the therapeutic purposes desired for the device. As illustrated in Figure 5, such a cable can have a central core 14 of a radiopaque material such as gold or platinum, thus dramatically enhancing the radiopacity of the cable. Even a solid super-elastic wire of the same diameter as the cable would have substantially less radiopacity than the cable of the invention with the central gold or platinum wire and the construction of the invention provides numerous other highly desirable characteristics. Among these characteristics is the relative flexibility and resistance to kinking of the cable compared to an equivalent single wire and substantially greater accommodation of the cable to bending, etc., with resultant

lessening of trauma to the surrounding tissue and ease of placement in a small body cavity.

While one presently preferred implementation of the micro-cable of the invention has been illustrated, those skilled in the art will appreciate that other variations of the invention may have advantages for certain purposes. Figure 6 is an example of one such construction 40 in which radiopacity is more desirable than in other forms and for that reason a number of radiopaque strands 42, in this illustration four in number, are formed into the cable along with three resilient material strands 44. It will also be appreciated that a larger or smaller number of strands may be incorporated into a given cable and the cables may be formed of multiple cables in order to provide desired bending and strength characteristics. It will also be appreciated by those skilled in the art that the invention is adaptable to the use of a variety of materials which by themselves would not have been easily adaptable to micro devices for interventional therapies. For instance, materials such as copper are useful for intrauterine devices and the like, but copper wire, even when heavily alloyed, has certain limitations for use in such devices. By use of the present invention, composite cables incorporating one or more strands of a desired material can be configured with other strands providing strength, flexibility, shape memory, super-elasticity, radiopacity or the like for previously unavailable characteristics in micro devices.

Figure 7 illustrates a cross-section of an additional presently preferred embodiment of the invention in which the strands 12, 14 of the micro-cable 10 are bundled and banded at intervals by bands 50 to produce a composite banded cable 52 in order to provide increased flexibility without unraveling or dislocation of the strands in the cable. Figure 8 is a perspective view of the banded cable 50 of this embodiment. While the illustrated configuration shows the strands being laid parallel within the cable, it is also possible in this construction to include both twisted cables as the primary cables 10 within the outer bands 50 to form the composite cable 52. This

configuration can use one or more longitudinal strands 14 which are radiopaque, thus providing a continuous indication of radiopacity within the cable. As a further alternative embodiment, it is possible for the longitudinal cable 52 to be formed of a single inner cable 10 with bands 50.

Figure 9 illustrates a further embodiment of the invention in which longitudinal strands of cables are contained within a wound cover 56 for the purposes of providing a composite guide wire or the like 58 having improved torqueability. Such a construction has particular advantages for guidewire designs having improved radiopacity in very small diameters. It will be appreciated that in this configuration, as well as the other longitudinally arranged multi-stranded cables, the number of strands and the degree to which they extend along the cable within the sheath is a variable which can be used to provide increased stiffness, pushability and torqueability in some sections with greater flexibility in others. Additionally, composite cables according to the invention can incorporate additional elements normally not available in solid guide wires, such as optical, thermal or ultrasound imaging elements, therapeutic agent delivery catheters, and can take advantage of materials which are not readily adaptable to prior art catheter or guide wire designs incorporating a primary wire structured element. Figures 10a and 10b illustrate a further variable available because of the invention; the exterior wrapped cover 56 can be wound at greater or lesser intervals 60 along the outside to provide variations in the torqueability and stiffness of the composite cable. Also, the thickness and width of the wrapping cover 56, as well as its material composition along the composite guide wire 58, can offer further capabilities for customizing the design for various applications. These advantages can be combined with the benefits of shape memory or super-elastic alloys to create guidewires and other devices with heretofore unavailable capabilities.

Figures 11 and 12 illustrate a cross-section of a micro-cable according to the invention which has at least one overall exterior sheath to contain the micro-cable. The micro-cable may be made of one or more multiple strand elements which

may further include twisted or longitudinal strands within their construction. The sheath may also be used to control the torqueability characteristics of the cable, and the sheath may be multi-layered with different materials in order to provide a graduated bending and stiffness characteristic over the length of the cable.

It will be appreciated that a three dimensional occlusive device adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery, can be formed as described above, from at least one multi-stranded micro-cable having a plurality of flexible strands of a resilient material, with at least one radiopaque strand to provide a radiopaque marker for the device during vascular surgery. The occlusive device is configured to have a first inoperable, substantially linear, elongated configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated.

In the method of making the vasoocclusive coils of the invention, a mandrel is used for annealing the coils in the desired second operable, substantially orthogonal three dimensional box or cube shape. A mandrel suitable for making such second operable, three dimensional shaped occlusive devices can be formed of a refractory material, such as alumina or zirconia, for example. The mandrel forms a support for the winding and heat treatment of the wound vasoocclusive device, whether formed from a single strand of platinum wire, a multi-stranded micro-cable, a plurality of micro-cables, or a composite micro-cable occlusive device as described above, and the mandrel ideally will not contaminate the occlusive device during heat treatment of the device.

In one presently preferred embodiment illustrated in Figures 13, 14 and 15, one or more of the flexible strands forming the vasoocclusive coil may be wound around the surface of a mandrel 70 having a substantially orthogonal main body 72 with six cylindrical posts 74 having a diameter slightly smaller than that of the main

body, disposed on the body and aligned with the three orthogonal x, y and z axes through the body of the mandrel, for aligning and shaping the distal portion of the vasoocclusive device as it is wound on the mandrel.

As is illustrated in Figures 16, 17 and 18, in one variant of the embodiment of Figures 13, 14 and 15, the mandrel may optionally also include an aperture, such as a threaded aperture 78, provided in a face 80 of one of the posts 74 and coaxially aligned with the orthogonal axis the post, for receiving a corresponding end 82 of a generally cylindrical handle 84. The end 82 of the handle may also be correspondingly threaded. The handle can optionally be used as a mandrel for winding a portion of the vasoocclusive coil with a helical shape.

Referring to Figures 19, 20 and 21, in another variant of the embodiment of Figures 13, 14 and 15, one or more of the flexible strands forming the vasoocclusive coil may be wound around the surface of a mandrel 70' having a substantially orthogonal main body 72' with five cylindrical posts 74' and a sixth cylindrical post 84' that is longer than the other five cylindrical posts, so as to allow the longer cylindrical post 84' to be used as a handle. The longer cylindrical post 84' additionally may be used as a mandrel for winding a portion of the vasoocclusive coil with a J-shaped coil portion or with a substantially helical shape as illustrated in Figures 3A and 3B. The six cylindrical posts are typically formed with the body as one piece, and each of the six cylindrical posts typically has a diameter slightly smaller than that of the main body. The six cylindrical posts are aligned with the three orthogonal axes through the body of the mandrel, for aligning and shaping the distal portion of the vasoocclusive device as it is wound on the mandrel, as is illustrated in Figure 20, to form the second operable, three dimensional box or cube-shaped configuration for occluding the desired portion of the vasculature to be treated.

The surface of the mandrel may also have one or more apertures for receiving one or more ends of the strands, to assist winding into the desired form. The wound occlusive device is preferably heat treated at a suitable temperature and a

sufficient period of time to impart the form to the shape memory material included in the device. While heat treatment at a temperature of about 1100° F for approximately 4 hours or more is typically sufficient to impart the form to the occlusive device when the shape memory material is a nickel titanium super-elastic alloy, although the temperature utilized can be substantially lowered, and the duration of heat treatment adjusted accordingly, as will be appreciated by those skilled in the art. After the heat treatment, the occlusive device is removed from the mandrel, and cold worked into the desired collapsed elongated configuration for placement into a catheter or cannula for use. When the occlusive device reaches its destination in the vasculature during vascular therapy, it assumes the primary shape imparted from the heat treatment on the mandrel.

It will be apparent from the foregoing that while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding a portion of the vasculature for use in interventional therapy and vascular surgery, comprising:

at least one strand of a flexible material formed to have a portion with a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, three dimensional orthogonal configuration for occluding the desired part of the vasculature to be treated.

2. The vasoocclusive device of Claim 1, further comprising a second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, coiled shape for filling and reinforcing the distal, three dimensional shaped portion when the vasoocclusive device is implanted at the site in the vasculature to be treated.

3. The vasoocclusive device of Claim 1, further comprising a second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, substantially J-shape for filling and reinforcing the distal, three dimensional shaped portion when the vasoocclusive device is implanted at the site in the vasculature to be treated.

4. The vasoocclusive device of Claim 1, further comprising a second portion having a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a

second operable, substantially helical coil shape for filling and reinforcing the distal, three dimensional shaped portion when the vasoocclusive device is implanted at the site in the vasculature to be treated.

5. The vasoocclusive device of Claim 1, wherein said vasoocclusive device is formed from at least one flexible strand of a resilient radiopaque material to provide a radiopaque marker of the deployed configuration of a device made of the strand during vascular surgery.

6. The vasoocclusive device of Claim 1, wherein said at least one strand comprises a super-elastic material.

7. The vasoocclusive device of Claim 1, wherein said at least one strand comprises a single strand of platinum wire.

8. The vasoocclusive device of Claim 1, wherein said at least one strand comprises a shape memory material.

9. The vasoocclusive device of either Claim 6 or Claim 8, wherein said at least one strand comprises a nickel-titanium alloy.

10. The vasoocclusive device of Claim 9, wherein said shape memory material is heat treated such that the shape memory material is highly flexible at a temperature appropriate for introduction into the body via a catheter, and after placement, the device will take on the primary coil configuration.

11. The vasoocclusive device of Claim 5, wherein said radiopaque strand comprises at least one centrally, axially disposed radiopaque wire.

12. The vasoocclusive device of Claim 5, wherein said radiopaque strand is made of platinum.

13. The vasoocclusive device of Claim 5, wherein said radiopaque strand is made of tungsten.

14. The vasoocclusive device of Claim 5, wherein said radiopaque strand is made of gold.

15. The vasoocclusive device of Claim 1, wherein said strand of flexible material is further formed into a helical shape which is the form of the first, inoperable, substantially linear configuration of the strand.

16. A method of making a vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery, said vasoocclusive device being formed from at least one strand of a flexible material formed to have a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a portion having a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated, the method comprising the steps of:

winding at least one strand of a flexible material about a an orthogonally shaped mandrel in a three dimensional orthogonal configuration of the vasoocclusive coil;

heating said at least one strand of a flexible material wound about the

mandrel for a sufficient period of time to impart the form to the material included in the device to form an operable, three dimensional configuration of the vasoocclusive coil;

removing the vasoocclusive coil from the mandrel; and

cold working the vasoocclusive coil into a desired elongated configuration for placement into a catheter or cannula for use.

17. The method of Claim 16, wherein the mandrel about which said at least one flexible strand forming the vasoocclusive coil is wound has a substantially orthogonally shaped body with a plurality of posts disposed on the body.

18. The method of Claim 17, wherein six posts are disposed on the body aligned with the three orthogonal x, y and z axes through the body of the mandrel, for aligning and shaping the distal portion of the vasoocclusive device as it is wound on the mandrel.

19. The method of Claim 17, wherein said body includes a handle, and further comprising the step of helically winding a portion of the vasoocclusive coil about the handle.

20. The method of Claim 17, wherein said main body is substantially orthogonal.

21. The method of Claim 17, wherein said main body is substantially cubical.

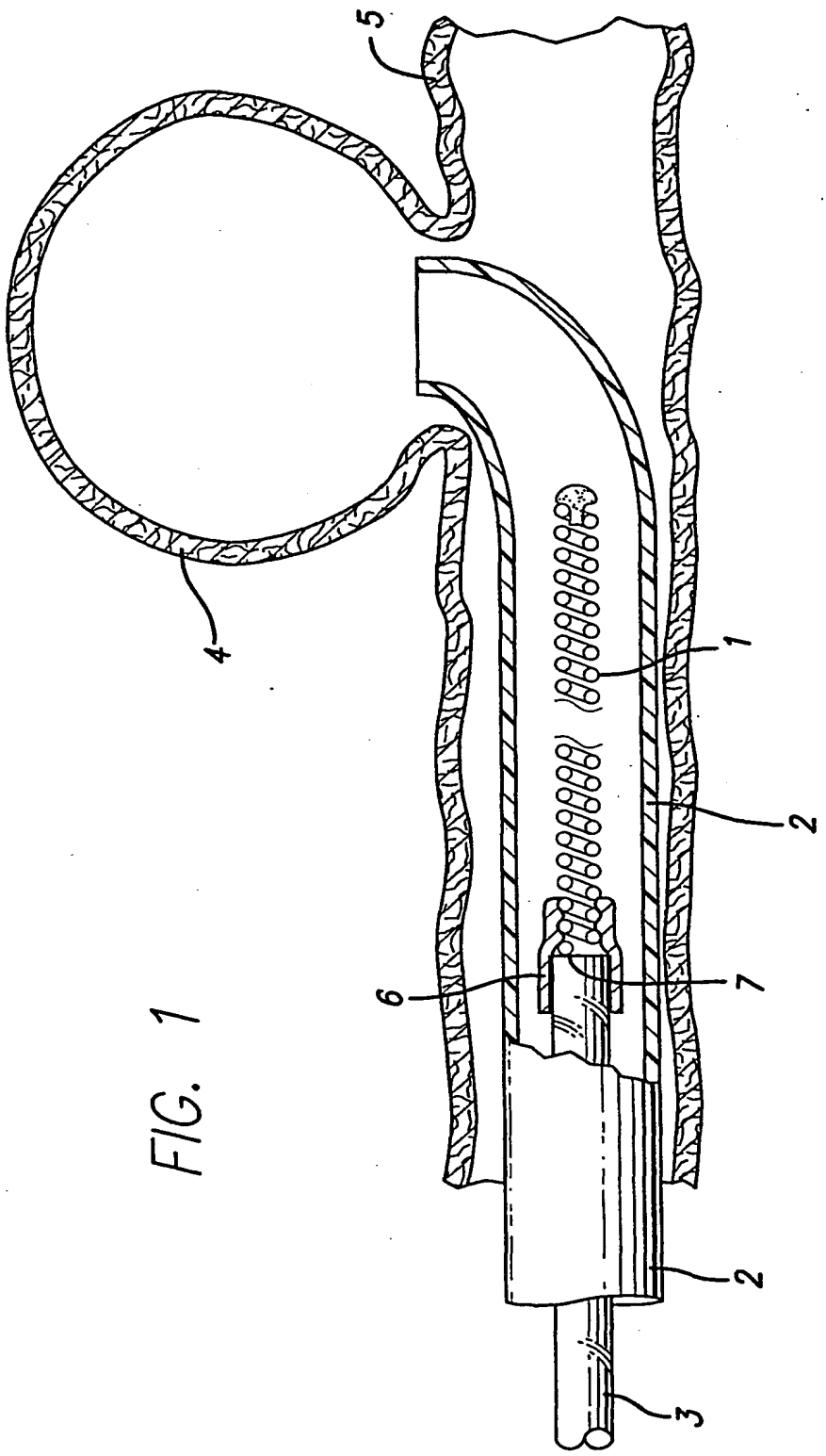

FIG. 1

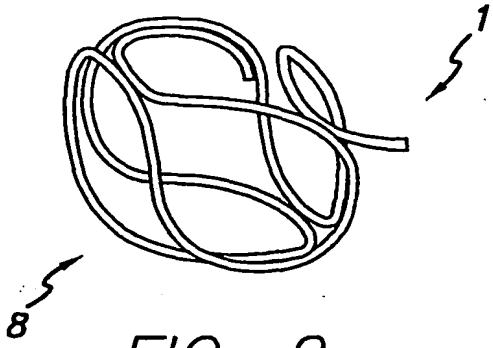

FIG. 2

FIG. 3A

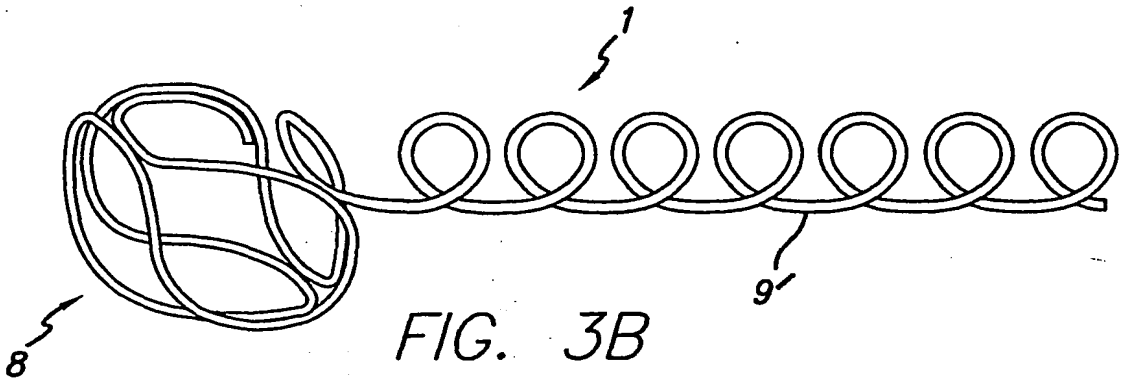

FIG. 3B

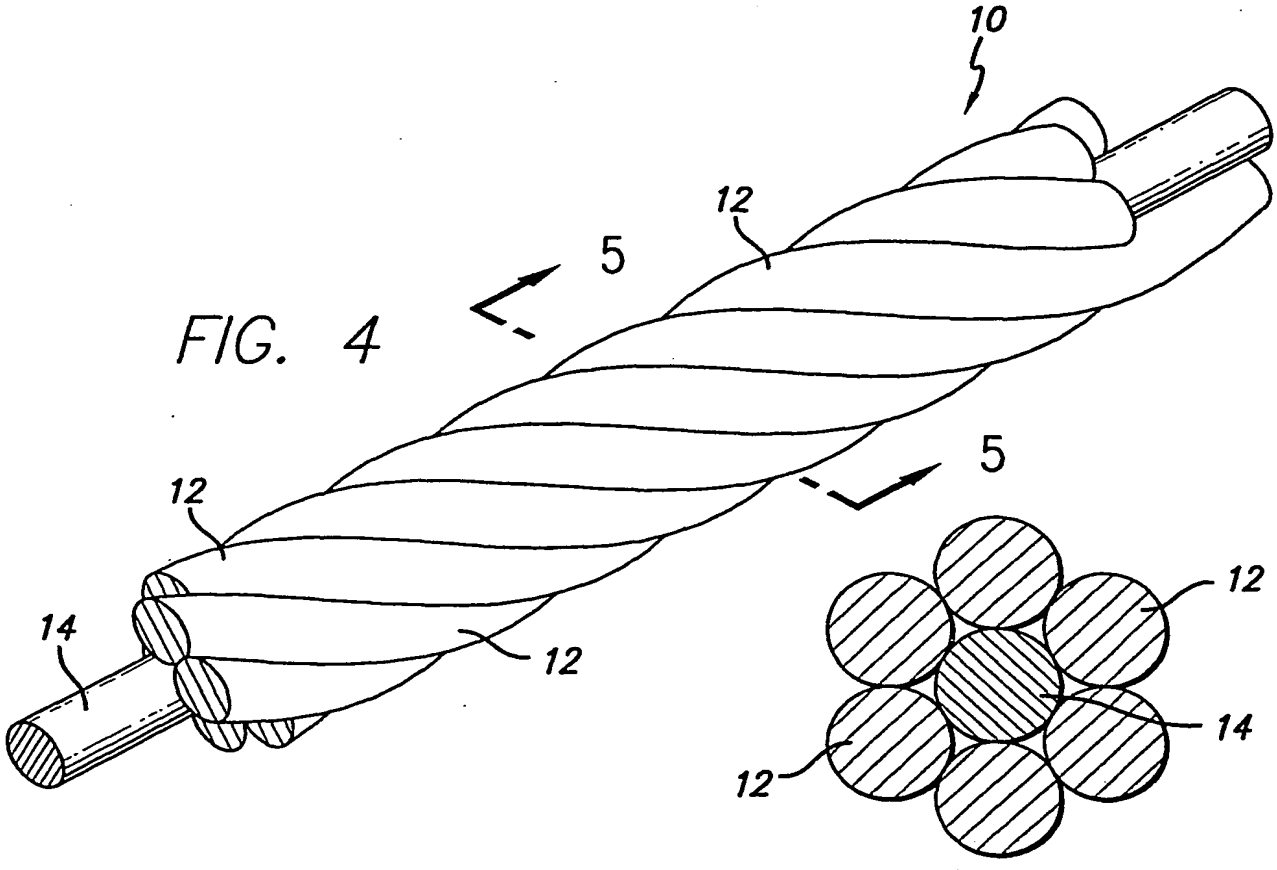

FIG. 4

FIG. 5

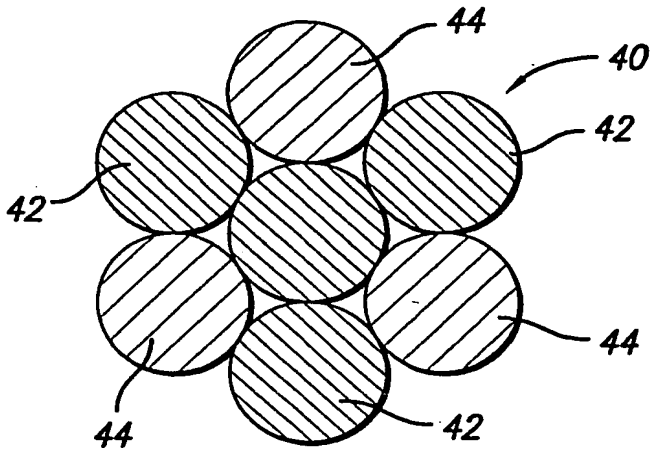

FIG. 6

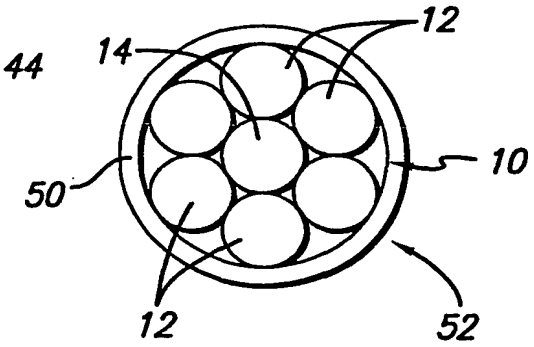

FIG. 7

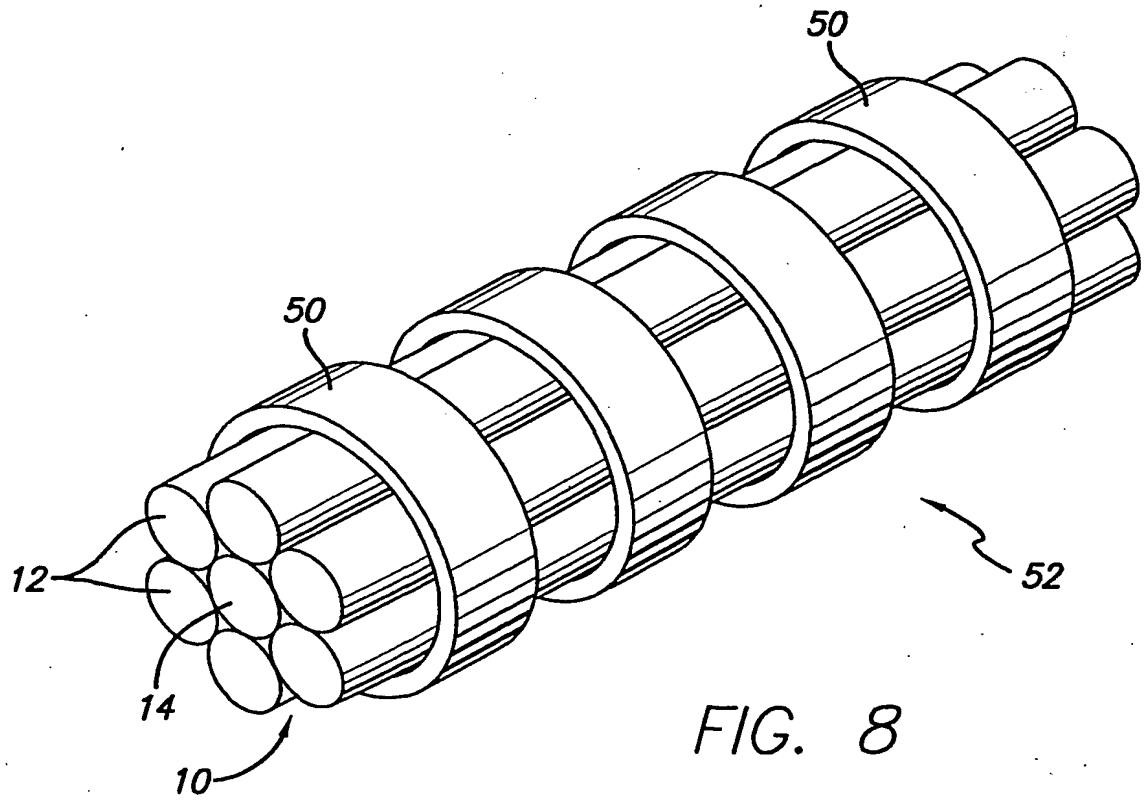

FIG. 8

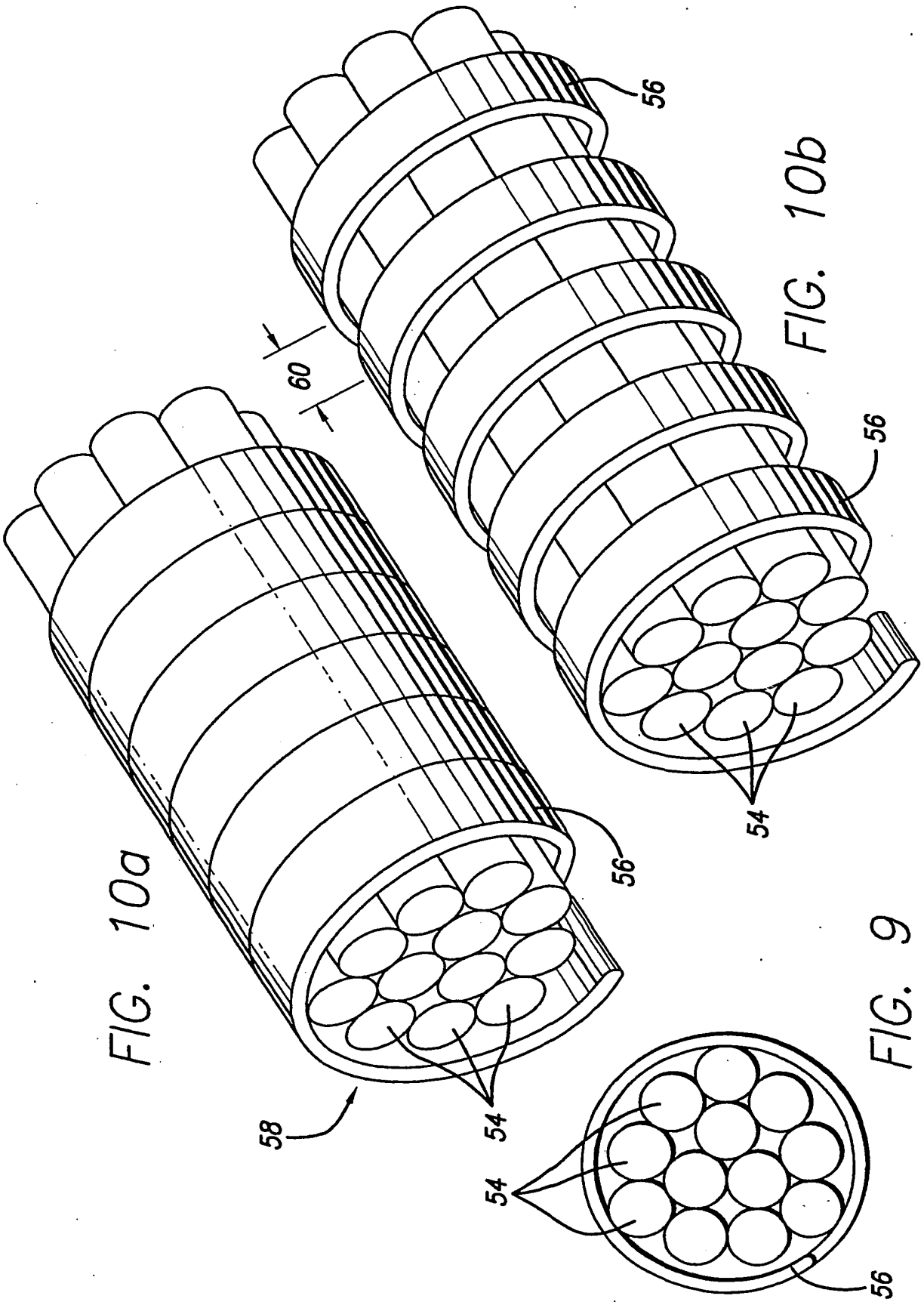

FIG. 10a

FIG. 10b

FIG. 9

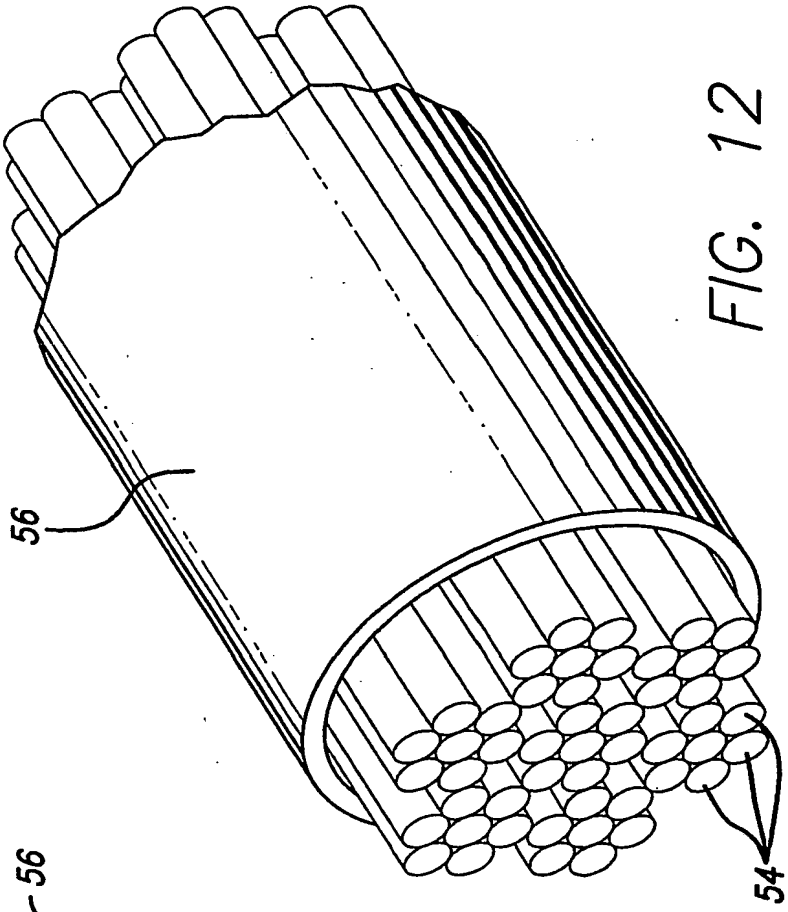

FIG. 12

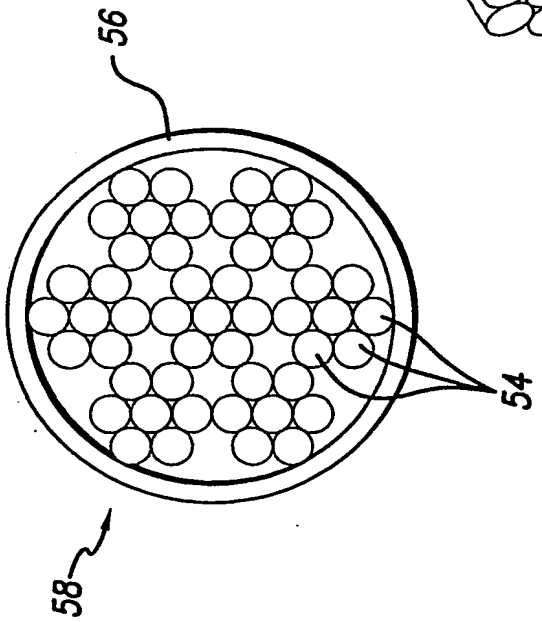

FIG. 11

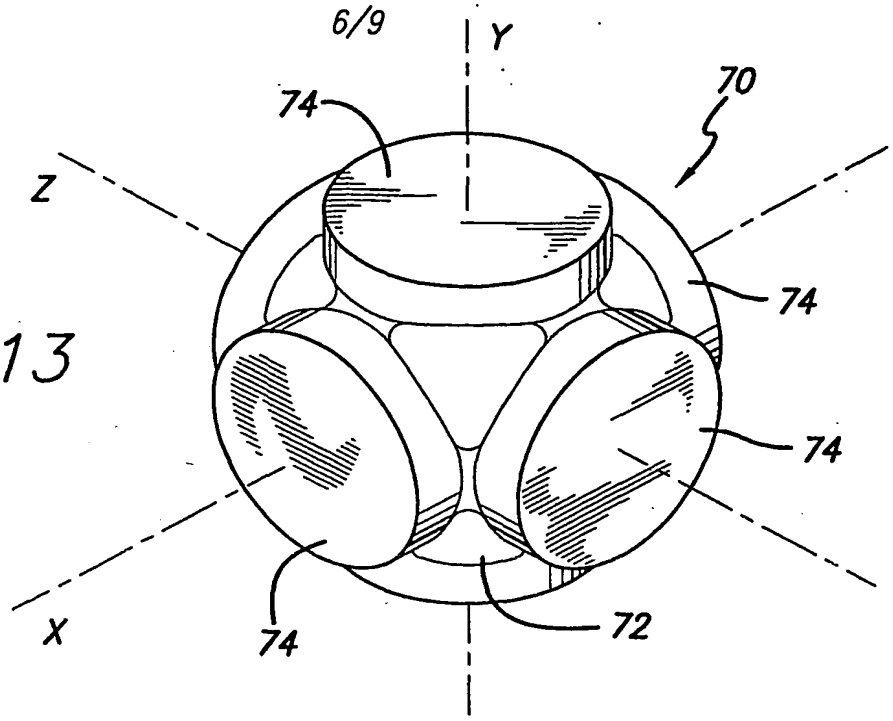

FIG. 13

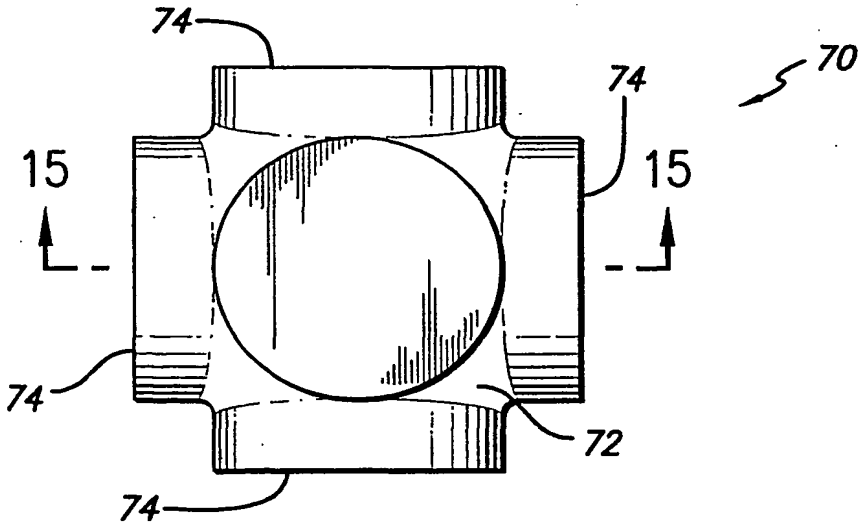

FIG. 14

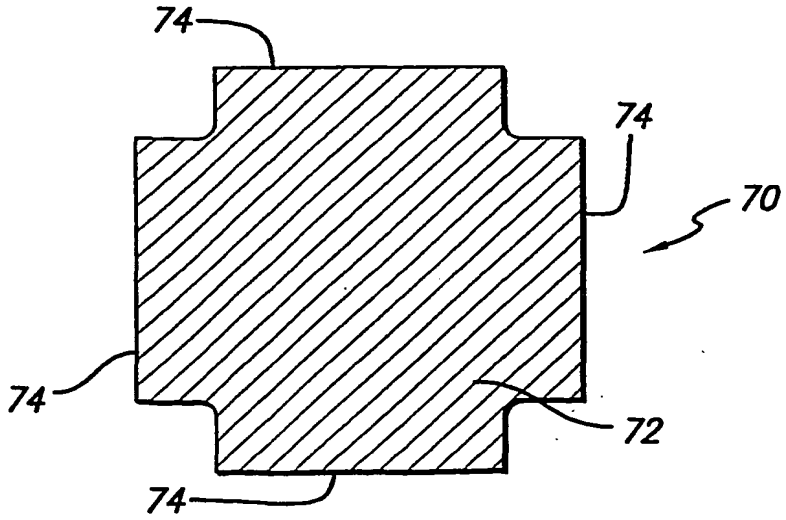

FIG. 15

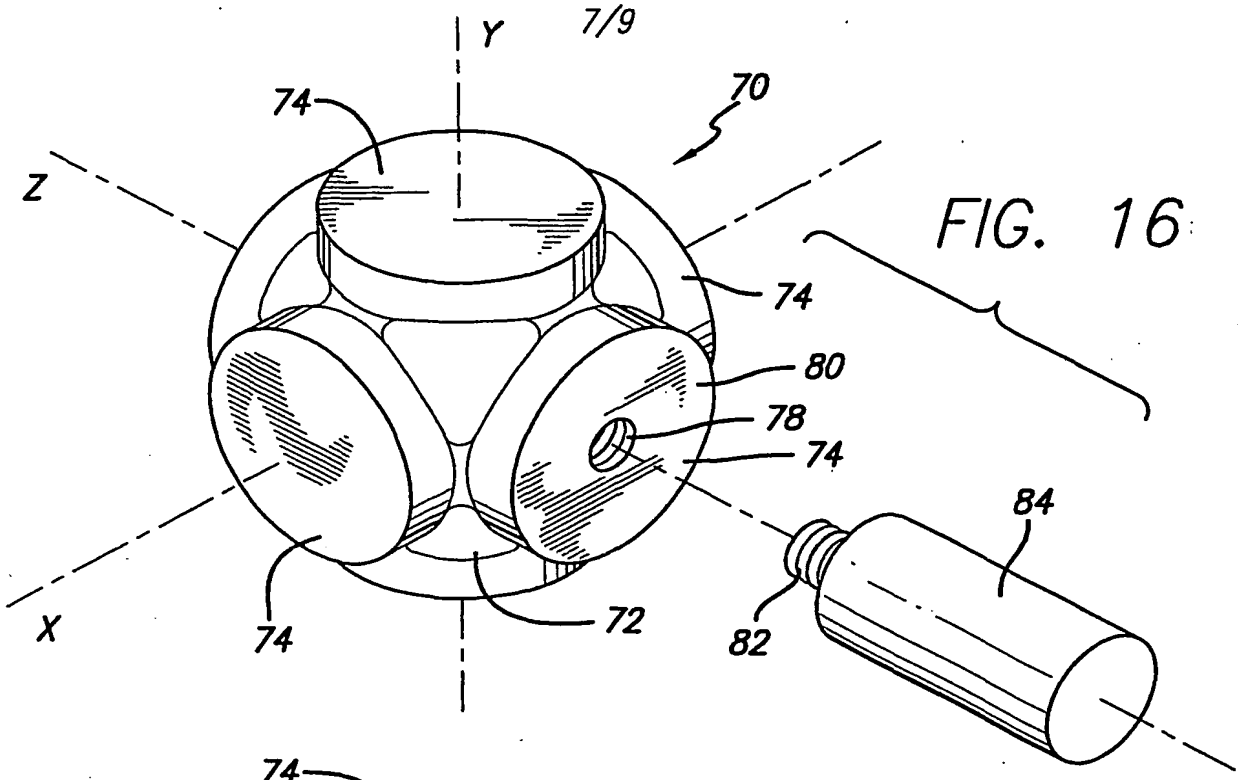

FIG. 16

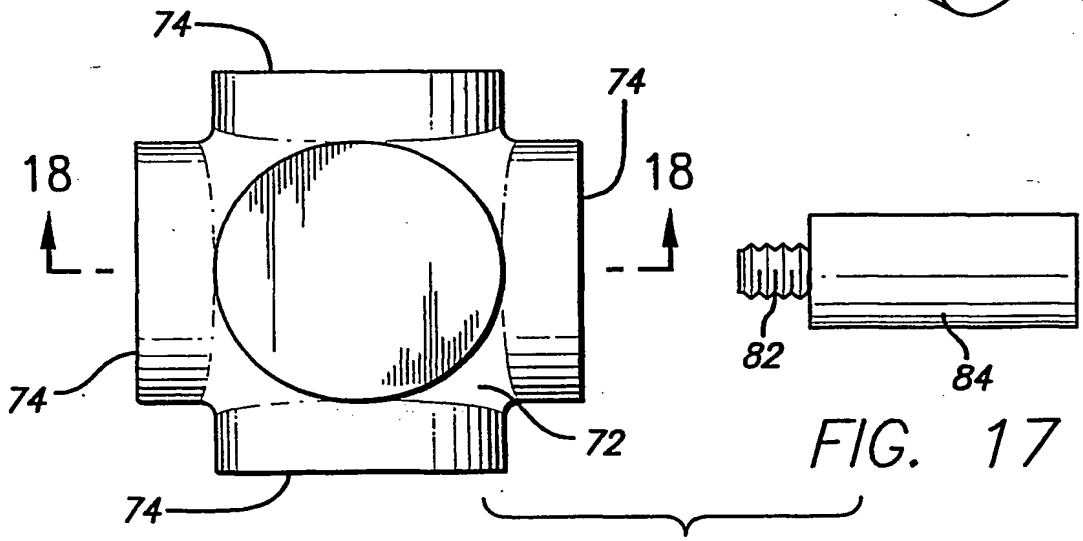

FIG. 17

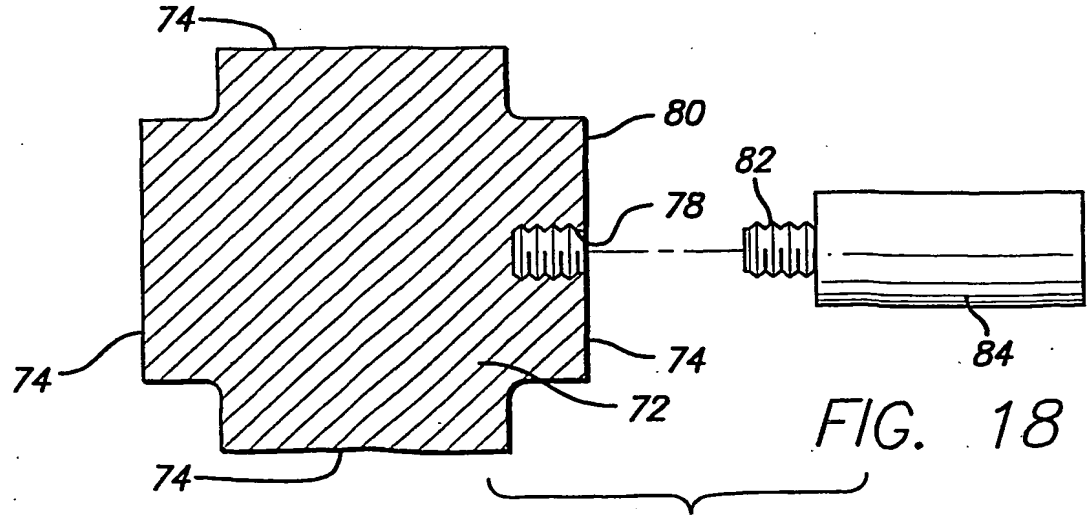

FIG. 18

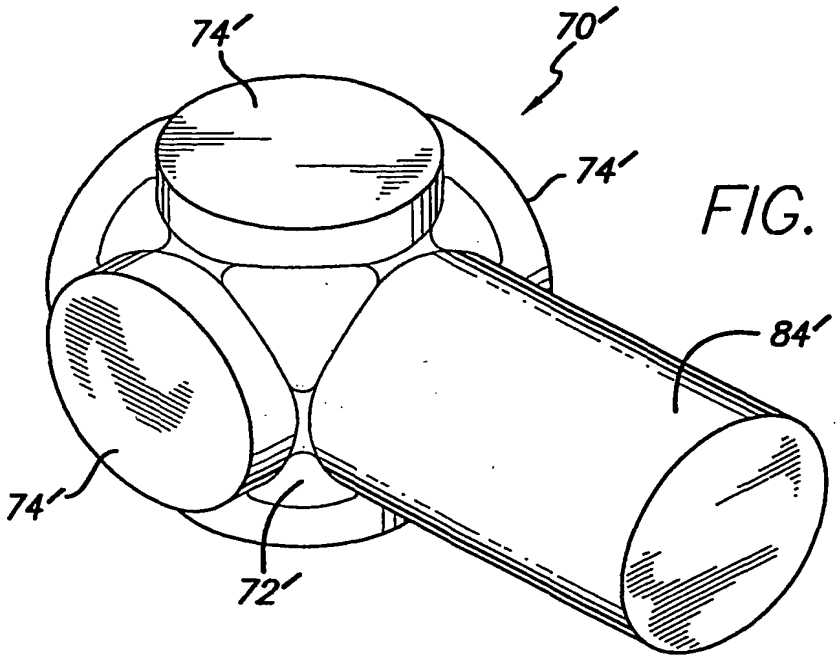

FIG. 19

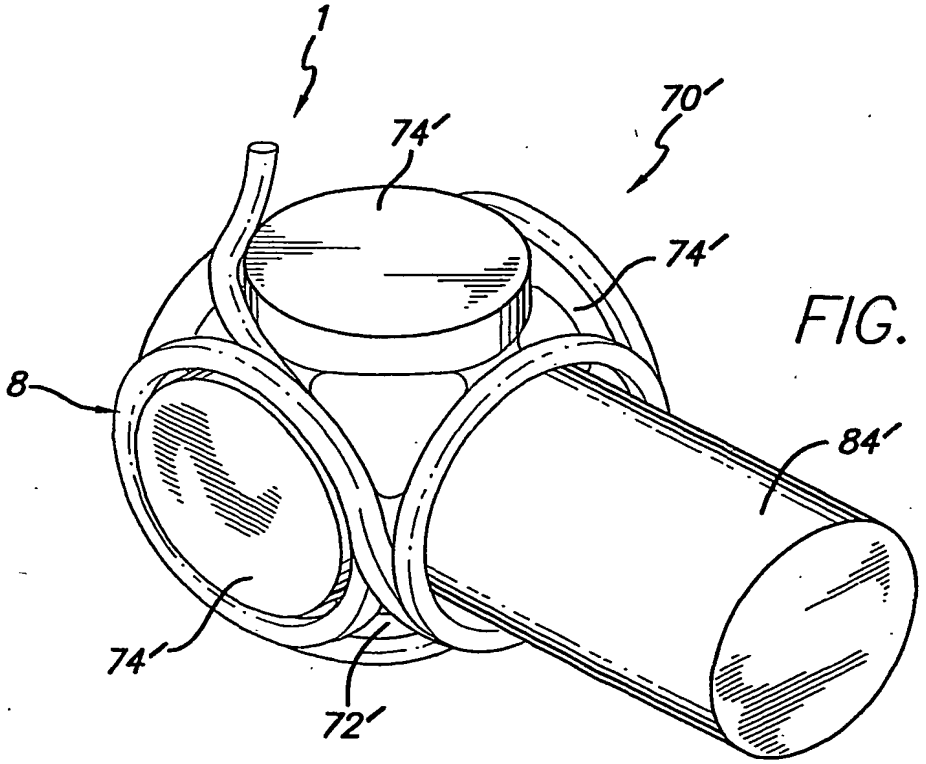

FIG. 20

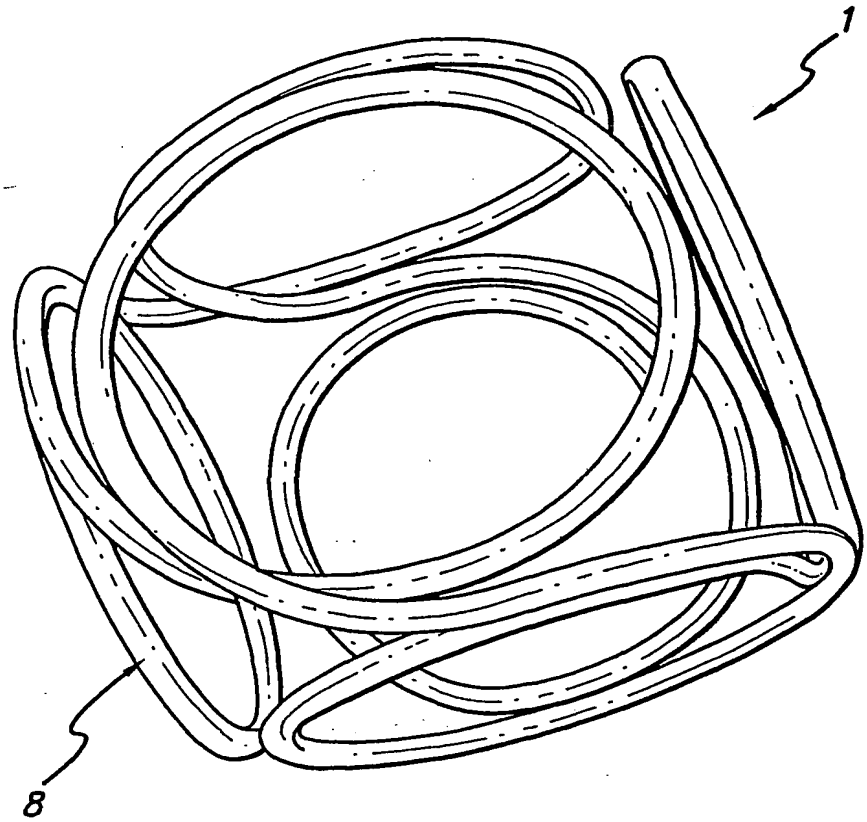

FIG. 21

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(74) Agents: **PAUL, James, W.** et al.; Fulwider Patton Lee & Utecht, LLP, Howard Hughes Center, Tenth Floor, 6060 Center Drive, Los Angeles, CA 90045 (US).

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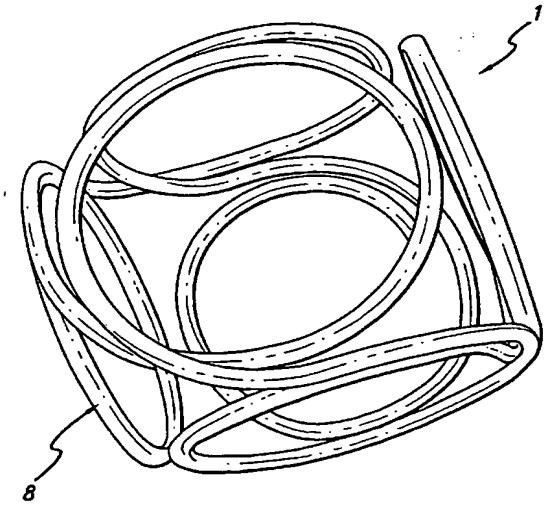
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: THREE DIMENSIONAL, LOW FRICTION COIL, AND METHOD OF MANUFACTURE



(57) Abstract: The three dimensional, low friction vasoocclusive coil (1) has a portion that is three dimensionally box or cubed shaped. The three dimensional box or cubed shaped portion (8) will form a basket for filling the anatomical cavity at the site in the vasculature to be treated. The vasooclusive device (1) is formed from at least one strand of a flexible material formed to have a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated. The vasoocclusive coil may optionally include a portion that is substantially J-shaped or helically shaped, for filling and reinforcing the three dimensional portion.

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(88) **Date of publication of the international search report:**
15 August 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/40892

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/12 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 29260 A (MICRUS CORP) 17 June 1999 (1999-06-17) page 22, line 7 -page 27, line 4 claims; figures	1,2,4-21
X	WO 00 10469 A (MICRUS CORP) 2 March 2000 (2000-03-02) claims; figures	1-15
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P,A	WO 00 35354 A (MICRUS CORP) 22 June 2000 (2000-06-22) claims; figures	1-21

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
1 February 2002	11/02/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Kuehne, H-C

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INTERNATIONAL SEARCH REPORT

International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 09893 A (BOSTON SCIENT LTD) 4 March 1999 (1999-03-04) claims	1-21
A	EP 0 765 636 A (TARGET THERAPEUTICS INC) 2 April 1997 (1997-04-02) claims; figures	1-21
A	US 5 536 274 A (NEUSS MALTE) 16 July 1996 (1996-07-16) claims	1-21

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Information on patent family members

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